K112118

NOV 17 2011

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510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193	
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6146 Fax: 847-534-6146	
Date Prepared:	08 November 2011	
Device Name:	Trade Name:	DREAMBOND
	Common Name:	Adhesive for Both Self and Total Etch Techniques
	Product Code:	KLE
	Classification Name:	Resin tooth bonding Agent
	Regulation Number:	21 CFR 872.3200
	Classification:	II
	Classification Panel:	Dental

Predicate Device:

DREAMBOND is substantially equivalent to Ace Bond SE from Bisco, Inc. Schaumburg IL (K063780) and to Adhesive EXL-759 from 3M ESPE AG Seefeld, Bavaria (K110302).

Indications for Use:

The indications of use of DREAMBOND are:

1. all direct restorations
2. all indirect restorations
3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure and composites)
4. desensitizing/sealing of tooth structure
5. protective varnish for glass ionomer fillings
6. priming of enamel for orthodontic use

Description of Applicant Device:

Bisco's DREAMBOND is a single-component dental bonding agent that combines etching, priming and bonding all in one bottle. DREAMBOND is an ethanol/water-based dental adhesive which bonds to dentin and to cut and uncut enamel. As a universal adhesive, DREAMBOND has been designed to work with light-cured, self-cured and dual-cured composite materials. DREAMBOND can be used for the bonding of both direct and indirect restorations. DREAMBOND may be used with or without phosphoric acid etchant.

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Technological Characteristics

The chemical components of DREAMBOND are based upon industry standard monomer chemistry and are found in legally marketed predicate device ACE Bond SE (K063780). A comparison of the chemical composition of DREAMBOND to the predicate device is provided.

Chemical Composition	**ACE Bond SE (K063780)**	**DREAMBOND**
Light-cured	X	X
Unfilled, multifunctional methacrylate resin	X	X
Ethanol and water based adhesive	X	X
Two component adhesive	X	
Single component adhesive		X

Performance Data:

They physical/mechanical properties of DREAMBOND were tested in the lab using ISO, ADA/ANSI, and Bisco Inc. QA/QC and R&D test protocols. The information provided in this 510(k) of DREAMBOND compared to ACE Bond SE demonstrates that DREAMBOND performs as well as or better than the predicate. A comparison of the physical and mechanical properties to the predicate device is included.

Physical / Mechanical Property Comparison	**ACE Bond SE (K063780)**	**DREAMBOND**
Low viscosity	X	X
Self-etching dental adhesive	X	X
Total-etch dental adhesive		X

Biocompatibility:

A biocompatibility evaluation was conducted to determine the safety of DREAMBOND using Oral Toxicity in Mice. No mortality or toxicity was observed for the tested time period. The conclusion of the safety evaluation and subsequent oral toxicity testing is that DREAMBOND is safe for its intended use.

Conclusion:

The information provided in this 510(k) submission demonstrates that DREAMBOND is substantially equivalent to the predicate devices Ace Bond SE (K063780) and to Adhesive EXL-759 (K110302) in terms of intended use, indications for use, chemical composition and physical properties.

It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

BISCO, Inc.
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www.bisco.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
BISCO, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

NOV 17 2011

Re: K112118
Trade/Device Name: DREAMBOND
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 8, 2011
Received: November 9, 2011

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

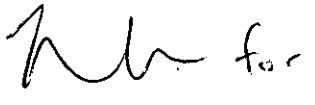
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K112118

Device Name: DREAMBOND

Indications for Use:

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1. all direct restorations
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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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